K111995 DEC 12 2011

510(k) Summary

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Device Information

Trade Name: Xing™ Spine System

Common Name: Pedicle Screw Spinal Fixation System

Classification Name: Pedicle Screw Spinal Fixation System

Product Code: MNH, MNI

Regulation Number: 21 CFR 888.3070

The date prepared: 7/11/2011

General Description

The Xing™ Spine System is a top-loading multiple component, posterior spinal fixation system which consists of pedicle screws, rods, set screws, and a cross link linking mechanism.

The Xing™ Spine System will allow surgeons to build a spinal implant construct to stabilize and promote spinal fusion. Xing™ Spine System implant components are supplied non-sterile are single use and are fabricated from titanium alloy (Ti-6Al-4V ELI) that conforms to ASTM F136. Various sizes of these implants are available. Specialized instruments are available for the application and removal of the Xing™ Spine System

Indication for Use

The Xing™ Spine System is a pedicle screw system indicated for the treatment of severe Spondylolisthesis (Grade 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion.

In addition, the Xing™ Spine System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine: degenerative Spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor and failed previous fusion (pseudarthrosis).

Materials:

The devices are fabricated from titanium alloy (Ti-6Al-4V ELI) that conforms to ASTM F136.

Performance Data (Bench Testing):

Mechanical testing as listed in **APPENDIX 3** that was conducted in accordance with ASTM F1717 demonstrates equivalence to the above predicate devices.

Mechanical test reports were completed for the following test methods:

- Static test: Tension, Compression and Torsion test report (ASTM F1717-09)
- Dynamic test: Fatigue test report (ASTM F1717-09)

Predicate Devices:

The subject device is substantially equivalent to the following predicate devices:

* OPTIMA™, Spinal System (U & I Co., Ltd; K001668)

* Global Spinal Fixation System (D.K.M. Co., Ltd; K031585)

* 4CIS® Vane Spine System (Solco Biomedical Co., Ltd.; K060702)

* Title®2 Spinal System(ENDIUS, INC; K041808)

* DELTA SPINAL FUSION SYSTEM(JEMO SPINE, LLC; K071857)

Comparison to Predicate Devices:

The subject device, Xing™ Spine System, is substantially equivalent to OPTIMA™, Spinal System manufactured by U & I Co., Ltd which was cleared for marketing as K031585 and the Global Spinal Fixation System manufactured by D.K.M. Co., Ltd which was cleared for marketing as K001668 and the 4CIS Vane Spine System manufactured by Solco Biomedical Co., Ltd which was cleared for marketing as K060702 and the Title®2 Spinal System manufactured by ENDIUS, INC. which was cleared for marketing as K041808 and DELTA SPINAL FUSION SYSTEM manufactured by JEMO SPINE, LLC which was cleared for marketing as K071857.

	Subject Device	Predicate Device	Predicate Device	Predicate Device	Predicate Device	Predicate Device
Company	Implanova co., Ltd	U & I Co., Ltd	D.K.M. Co., Ltd	Solco Biomedical Co., Ltd	ENDIUS, INC.	JEMO SPINE, LLC

Device Name	Xing™ Spine System	OPTIMA™, Spinal System	Global Spinal Fixation System	4 CIS VANE Spine System	Title®2 spinal system	DELTA SPINAL FUSION SYSTEM
510(k) Number	N / A	K001668	K031585	K060702	K041808	K071857
Device Classification Name	Orthosis, Spondyloisthesis Spinal Fixation	Orthosis, Spondyloisthesis Spinal Fixation	Orthosis, Spondyloisthesis Spinal Fixation	Orthosis, Spondyloisthesis Spinal Fixation	appliance, fixation, spinal interlaminal	orthosis, spinal pedicle fixation
Classification Product Code	MNH, MNI	MNH, MNI	MNH, MNI	MNH, MNI	MNH, MNI, NKB	MNI
Regulation Number	888.3070	888.3070	888.3070	888.3070	888.3050	888.3070
Intended Use	See the indications for use statement	Identical	Identical	Identical	Identical	Identical
Material	Ti-6AI-4V ELI	Ti-6AI-4V ELI	Ti-6AI-4V ELI	Ti-6AI-4V ELI	Ti-6AI-4V ELI	Ti-6AI-4V ELI
Product Parts	Pedicle Screw, Rod(Straight type & curved type), Nut, Transverse Link	Pedicle Screw, Rod(Straight type & curved type), Set Screw, Transverse Link	Pedicle Screw, Rod(Straight type & curved type), Connector, Transverse Link	Pedicle Screw, Rod, Set Screw, Transverse Link(Identical)	Pedicle Screw, Rod, Set Screw, Connetor	Pedicle Screw, Rod, Set Screw
Size of pedicle screw	4.0, 4.5, 5.0, 5.5, 6.0, 6.5, 7.0, 8.0 in diameter and from 20 to 55mm in a 5mm increment	5.0, 6.0, 7.0, 7.5, 8.0mm diameter in 30, 35, 40, 45, 50, 55mm length	5.0, 6.0, 7.0, 7.5, 8.0mm diameter in 30, 35, 40, 45, 50, 55mm length	4.0, 4.5, 5.5, 6.5, 7.5, 8.0, 8.5mm diameter in 25~60mm length(Similar)	-	-
Pre-Bending Rod	Available	-	-	Available	-	-
The amount of angulation possible					60°	86°

Any differences between the subject devices and the predicate devices will not affect safety or efficacy. Please see APPENDIX 2 Predicate Device Information that contains:

- K001668, K031585/K06072 Summary of Safety & Effectiveness documents
- OPTIMA™, Spinal System/Global Spinal Fixation System/4CIS Spine System product literatures

Based on the comparison between the subject and predicate devices provided in Table 3, IMPLANOVA Co., Ltd believes that the Xing™ Spine System is substantially equivalent to the predicate devices.

Conclusion

Testing and other comparisons have established that the Xing™ Spine System is substantially equivalent in design, materials, indications, and performance to other predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

DEC 12 2011

Implanova Co., Ltd.
% Kodent, Inc.
Ms. April Lee
325 North Puente Street, Unit B
Brea, California 92821

Re: K111995
Trade/Device Name: Xing™ Spine System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class II
Product Code: MNH, MNI
Dated: November 30, 2011
Received: December 06, 2011

Dear Ms. Lee:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

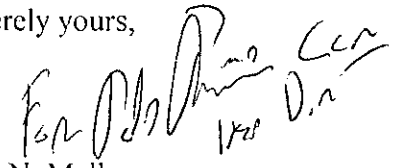
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(K) Number (if known): K111995

Device Name: Xing™ Spine System

Indication for Use:

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Prescription Use _____x_____ AND/OR Over-The-Counter _____

(Part 21 CFR 801 Subpart D) (Per 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K111995